## REMARKS

Reconsideration of the rejections based upon the foregoing amendments and the following remarks is respectfully requested.

### A. Allowable Subject Matter

Applicants would like to thank the Examiner for indicating that claims 18 and 20 contain allowable subject matter, but were objected to as being dependent upon a rejected base claim. Claims 18 and 20 have been amended herein to be in independent form, therefore it is respectfully submitted that they are now nonobjectional

### B. Claims 1 and 4-7 were rejected under 35 U.S.C. §102(b) as being anticipated by Blackmer (US 3,661,748).

Claim 1 has been canceled herein, therefore its rejection under 35 U.S.C. §102(b) is now moot.

Claim 2 specifically requires the steps of "a) applying a signal having an AC component to the sensor; b) measuring an AC response to the signal; and c) using the AC response to determine if the sensor is abused, wherein steps (a), (b) and (c) are performed before application of the biological fluid to the sensor." It is respectfully submitted that the cited reference does not teach or suggest the above-recited elements of Applicants' claim 2.

The Final Office Action did not specifically address the limitations of claim 2; however, it is clear that the Blackmer device only works when there is fluid sample surrounding the electrode. For example, Blackmer describes the fault sensor thusly:

"The system for detecting a sensor fault comprises means for providing an electrical connection to the conductive fluid, means [sic] to apply an AC signal to the electrical connection, an AC signal detector connected to the DC circuitry, and a threshold circuit responsive to the output of the AC signal detector for providing an output signal indicative of a fault in the electrochemical sensor system when the AC signal detector has an output that differs by a predetermined amount from a normal value."

(col. 1, ll. 46-55, emphasis added). Additionally , the structure and testing methodology is further described as:

"The system shown in FIG. 1 includes structure 10 having inlet and outlet passage 12 and 14 and a chamber 16 in which a fluid sample may be positioned. Two electrode systems are positioned for insertion into contact with the fluid in chamber 16, a $p0_2$ electrode system 20 and a $pCO_2$ electrode system 22. . . . An AC signal from oscillator 80 is applied to these electrode systems, the signal being applied to electrode 82 that is in contact with chamber 16 and to electrode 84 in chamber 60 (or alternatively to reference electrode 68). Should either membrane 30 or 32 leak, the liquid in chamber 16 can affect the accuracy of the reading. As each membrane is an excellent insulator when it is of proper integrity, only a minute AC current can flow from electrode 82 through either membrane 30 or 32 and electrodes 38 and 40 to the measuring circuit. However, if the liquid in chamber 16 contains ions, when a leak develops, sufficient AC current can flow through the leak to produce a significant AC voltage across resistor 85. This resulting signal is amplified by an amplifier 86, rectified by rectifier 88 and applied to the threshold circuit 90 so that when the AC signal exceeds a fixed magnitude, threshold circuit 90 produces an output indicating a defect in the electrode system."

(col. 2, l. 23 thru col. 3, l. 4, emphasis added).

As can be seen, the operation of the Blackmer device depends on the presence of the sample liquid containing ions being in chamber 16, as well as a leak through one of the membranes allowing the sample liquid to cross the membrane and carry AC current with it. The

sample liquid is the only conductor of the AC signal. In contrast, Applicants' claim 2 specifies that detection of an abused sensor occurs "before application of the biological fluid to the sensor." It is therefore respectfully submitted that claim 2 is allowable in view of the references of record.

Claims 4-7 depend from claim 2 and therefore include all of the limitations of claim 2. It is therefore respectfully submitted that claims 4-7 are allowable over the references of record for at least the same reasons set forth above with respect to claim 2.

**C. Claims 1-17, 19 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over White (US 5,352,351) in view of Blackmer.**

Claim 1 has been canceled herein, therefore its rejection under 35 U.S.C. §103(a) is now moot.

Claim 2 specifically requires the steps of "a) applying a signal having an AC component to the sensor; b) measuring an AC response to the signal; and c) using the AC response to determine if the sensor is abused, wherein steps (a), (b) and (c) are performed before application of the biological fluid to the sensor." It is respectfully submitted that the cited references do not teach or suggest the above-recited elements of Applicants' claim 2.

The Office Action alleges that it "would have been obvious to one of ordinary skill in the art at the time the invention was made to adapt the failsafe procedure of White to incorporate the AC fault measurements of Blackmer because of the ability to detect faulty sensors in a variety of formats as taught by Blackmer" (Office Action, p.4, first full paragraph).

1. Obviousness Generally

The White and Blackmer references are not properly combinable under 35 U.S.C. §103(a). "To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be a suggestion or motivation, either the references themselves or the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or the references when combined) must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be both found in the prior art, and not based on the applicant's disclosure." Manual of Patent Examining Procedure (MPEP) §2142 citing *In Re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The seminal case directed to application of 35 U.S.C. §103 is *Graham v. John Deere*, 383 U.S. 1; 148 USPQ 459 (1966). From this case, four familiar factual inquiries have resulted: (1) determining the scope and contents of the prior art; (2) ascertaining the differences between the prior art and the claims in issue; (3) resolving the level of ordinary skill in the pertinent art; and (4) evaluating evidence of secondary considerations. The first three are directed to the evaluation of prior art relative to the claims at issue, and the last is directed to evaluating evidence of secondary considerations. *See* MPEP §2141.

Recently, the U.S. Supreme has further clarified the Graham analysis in view of the Federal Circuit's teaching, suggestion, or motivation test in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. ____ , 82 USPQ2d 1385 (2007). "When it first established the requirement of demonstrating a teaching, suggestion, or motivation to combine known elements in order to

show that the combination is obvious, the Court of Customs and Patent Appeals captured a helpful insight. ... a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art" *KSR Int'l*, 550 U.S. ____ , 82 USPQ2d 1385, 1396 (2007, citations omitted). In *KSR*, the Supreme Court rejected a rigid application of the teaching, suggestion or motivation test (TSM), but did require a reasoned explanation of the reasons to make the alleged combination. The Supreme Court stated that "to facilitate review, this analysis should be made explicit. *See In re Kahn*, 441 F.3d 977, 988 CA Fed. 2006) ('[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness')." *KSR*, 82 USPQ2d at 1396.

Importantly, it is well known that the Examiner cannot merely state that modifications of the prior art to meet the claimed invention would have been "'well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art. MPEP § 2143.01(IV) (*citing Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993)). Such an assertion is "not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references." MPEP § 2143.01(IV).

2. The Cited References Teach Away from Their Combination

References cannot be combined if the references themselves teach away from their combination. MPEP § 2145(X)(D)(2) (*citing In re Grasselli*, 713 F.2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983)). "[I]t can be important to identify a reason that would have prompted a

person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). "A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.* "[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *Id.*

As conceded in the Office Action, White does not teach the use of signals having an AC component. The Office Action attempts to cure this deficiency by combining White with Blackmer, who teaches "the ability to detect faulty sensors" using AC signals. The Final Office Action did not specifically address the limitations of claim 2; however, it has been demonstrated in Section B above that the AC leakage test of Blackmer only works when there is an ion-containing fluid sample surrounding the electrode, and Blackmer teaches that the fluid sample is applied to the electrodes prior to checking for the AC leakage current. Conversely, White teaches that his failsafe procedure should be performed prior to the application of the sample (see, for example, col. 4, ll. 51-68). Therefore, the White and Blackmer references teach away from their combination, as White directs the failsafe test to be performed prior to sample application and Blackmer directs that the leakage test be performed after sample application.

3. It is not obvious to use DC and AC in a test using reagents

The biosensors of White all comprise electrochemical cells that use DC signals to test for analytes, wherein the DC responses are generated via reactions (usually enzymatic) that require

reagents. The AC signal responses detected by Blackmer are generated directly from the parameters of interest (presence of the sample fluid leaking across the membrane): they are direct measurements of physical properties without a specifying reagent. There is no teaching, suggestion or motivation in the art, nor would it be obvious to try, to use both DC signals and signals having an AC component together in the same environment, in the presence of a reagent, and with the same electrodes. It is recognized by Applicants that claim 2 does not require a DC signal or a reagent, but the White reference relates to DC tests conducted in the presence of a reagent, therefore it would not be obvious to use the AC methods of Blackmer, which do not use reagents, with these DC reagent-based tests. Therefore, one skilled in the art would not be motivated to combine the tests as suggested by the Examiner, and the combination of references relied upon in the Office Action do not render Applicant's invention obvious.

4. A Combination of the Cited References Does Not Teach Applicants' Claim 2

Claim 2 specifically requires the steps of "a) applying a signal having an AC component to the sensor; b) measuring an AC response to the signal; and c) using the AC response to determine if the sensor is abused, wherein steps (a), (b) and (c) are performed before application of the biological fluid to the sensor." It is respectfully submitted that the cited references do not teach or suggest the above-recited elements of Applicants' claim 2.

A combination of Blackmer and White would result in either the device of Blackmer utilizing the failsafe test of White, or the device of White utilizing the AC signal of Blackmer. The Office Action is not specific as to how the references are to be combined.

If using the device of Blackmer and the failsafe test of White, Blackmer teaches that the fluid sample is applied to the electrodes prior to checking for the AC leakage current. Upon reading the leakage current, the mathematical analysis taught by White would be used to interpret the data. This therefore does not meet Applicants' claim 2 limitation that the abused sensor test be performed "before application of the biological fluid to the sensor."

If using the White device and failsafe test modified with the Blackmer AC signal, it has been demonstrated in Section B above that the AC leakage test of Blackmer is only shown to work when there is a fluid sample surrounding the electrode, and Blackmer specifically teaches that the fluid sample is applied to the electrodes prior to checking for the AC leakage current. There is no teaching in either reference of a medium to carry the AC signal from one electrode to the other except the applied fluid sample. The combination therefore teaches that the fluid sample be applied to the electrodes of White, an AC signal applied to the electrodes, and analysis of the resulting response using the mathematical methodology taught by White. This therefore also does not meet Applicants' claim 2 limitation that the abused sensor test be performed "before application of the biological fluid to the sensor."

Therefore, in any configuration a combination of Blackmer and White teaches that the sample must first be applied to the electrodes and then the White quality check performed using the AC excitation signal of Blackmer. This does not teach Applicants' claimed abused sensor test "before application of the biological fluid to the sensor." Therefore, it is respectfully submitted that Applicants' claim 2 is allowable in view of the references of record.

Claims 3-7 depend from claim 2 and therefore include all of the limitations of claim 2. It is therefore respectfully submitted that claims 3-7 are allowable over the references of record for at least the same reasons set forth above with respect to claim 2.

Claims 8-17, 19 and 21 have been canceled herein, therefore their rejection under 35 U.S.C. §103(a) is now moot.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance, and respectfully request such action. Applicants respectfully request that the Examiner telephone the undersigned attorney for Applicants at 317-634-3456 if the Examiner does not find that all claims are in condition for allowance as presented herein.

Respectfully submitted,

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